

INITIAL ASSURANCE

Regarding Procedures for Dealing with and Reporting Possible Misconduct in Science

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Place mailing label here.

If the address area to the left is blank, please fill in your institution's name and address. If the address was completed for you, please make any necessary corrections.

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Each institution which receives or applies for a research, research-training, or research-related grant or cooperative agreement under the Public Health Service Act must submit an annual assurance certifying that the institution has established administrative policies as required by the Final Rule (42 CFR Part 50, Subpart A), and that it will comply with those policies and the requirements of the Final Rule as published at 54 FR 32446, August 8, 1989.

1. In accordance with 42 CFR Part 50, the administrative policies must provide for the following, and otherwise comply with 42 CFR 50.101-50.105:
 - An impartial process for receipt of allegations of scientific misconduct and for initiating immediate inquiry into each allegation.
 - Subject to Part 50, completion of each inquiry within 60 calendar days from receipt of allegation, including preparation of a written report.
 - Maintenance of detailed documentation of an inquiry for at least three (3) years, which must, upon request, be provided to authorized HHS personnel.
 - Initiation of an investigation within 30 calendar days of the completion of an inquiry, if findings from that inquiry provide sufficient basis for conducting an investigation.
 - Subject to Part 50, completion of an investigation within 120 calendar days.
 - Selection of impartial experts to conduct inquiries and investigations.
 - Precautions against real or apparent conflicts of interest in an inquiry or an investigation.
 - Affording the affected individuals(s) confidential treatment to the maximum extent possible, a prompt and thorough investigation, and an opportunity to comment on allegations and findings of the inquiry and /or the investigation.
 - Notification to the Office of Research Integrity (ORI), PHS, that an investigation will be conducted.
 - Notification to ORI within 24 hours of obtaining a reasonable indication of possible criminal violations.
 - Preparation and maintenance of the documentation to substantiate an investigation's findings for at least three (3) years after PHS acceptance of the final report.
 - Taking appropriate interim administrative actions to protect Federal funds and ensure that the purposes of the Federal financial assistance are being carried out.
 - Promptly advising ORI of any developments during the course of the investigation which disclose facts that may affect current or potential Department of Health and Human Services funding for the individual(s) under investigation or that the PHS needs to know to ensure appropriate use of Federal funds and otherwise protect the public interest.
 - Making efforts to restore the reputations of persons alleged to have engaged in misconduct when allegations are not confirmed.
 - Protecting, to the maximum extent possible, the positions and reputations of those persons who, in good faith, make allegations of scientific misconduct.
 - Imposing appropriate sanctions on individuals when the allegation of misconduct has been substantiated.
 - Notifying the ORI of the final outcome of the investigation with a written report that thoroughly documents the investigative process and findings.
 - Informing its scientific and administrative staff of the policies and procedures and the importance of compliance with those policies and procedures.

2. Name and Title of Official Signing for the Organization _____ | Telephone _____
| () _____

Address _____

I certify that:

- (a) this organization has established--and will comply with--policies and procedures, incorporating the provisions set out in Item 1 above, for inquiring into and investigating allegations of scientific misconduct.
- (b) this organization will comply with the requirements of the PHS regulations on responsibilities of awardee and applicant institutions for dealing with and reporting possible misconduct in science (42 CFR, Part 50, Subpart A); and
- (c) this organization will provide its policies and procedures to the Public Health Service upon request.

Signature of the Person named in Item 2. (*In ink. "Per" signature not acceptable.*) _____ | Date _____
| _____

Instructions for Completing Form PHS-6315
“Initial Assurance Regarding Procedures for Dealing with and Reporting Possible Misconduct in Science”

Who Should Submit This Form--

Complete this form only if your organization has not previously submitted an assurance, and only if your organizational component is not covered under an assurance submitted, or being submitted, by a central office in your institution.

Only one assurance is to be submitted for each organization or institution.

Where major components (e.g., college of life sciences, school of medicine, department of pathology, research institute, etc.) have their own uniquely tailored scientific misconduct policies, the overall institutional/organizational assurance certifies that *all* the various policies are in compliance.

Use this form only for the initial assurance from your institution. A separate form will be used for the annual update.

Pre-printed Copies of This Form--

Each institution that has received PHS scientific support in Fiscal Year 1988 or later, or that has an application for support under consideration at the time this form is initially distributed, will be sent a form pre-printed with its address and a PHS institutional code (IPF Number). Please use this pre-printed form to facilitate integration of assurance information into PHS records. All mailings regarding assurances will be sent to the institutional address on the pre-printed form, even though the official signing the assurance may have a different address.

If you have not received a pre-coded form, but believe you should have, please check with the central administration of your institution to determine if your organization is covered under an already submitted assurance. If it is not, you should complete an uncoded form.

Before You Sign Your Assurance--

Make sure you have carefully reviewed all the requirements contained in the Final Rule. The provisions listed on the assurance form are included to assist you in making sure that your policies are complete, but they do not supersede the provisions of the Final Rule.

Be aware that your institution will be held responsible for the compliance of any organization that receives PHS support through your institution (e.g., other institutions in a consortium where your institution is the grantee). You must ensure that entities with which your institution has such consortium or contractual arrangements have an assurance on file with the Office of Research Integrity, or have agreed to be subject to the policies of your institution with respect to the research supported through the consortium or contractual arrangement.

You should also have reviewed and placed on file, all the policies of your institution established under the assurance and the Final Rule, along with documentation regarding sub-awardee arrangements. Up-to-date copies of these policies, along with the names(s) of the individual(s) with operational responsibility for scientific misconduct policy implementation, should be kept on file.

Address for Submission--

Mail your completed assurance to: **Assurance Program**
Office of Research Integrity
OPHS - RW II 700
5515 Security Lane
Rockville, MD 20852